



STATE OF INDIANA

Request for Information 11-2

INDIANA DEPARTMENT OF ADMINISTRATION

On Behalf Of

**Indiana Family and Social Services
Administration**

and

Indiana Cord Blood Bank

Solicitation For:

Operation of the Indiana Cord Blood Bank

Response Due Date July 23, 2010

Stephanie Taylor, Contract Manager
Indiana Department of Administration
Procurement Division
402 W. Washington St., Room W478
Indianapolis, Indiana 46204

REQUEST FOR INFORMATION 11-2

INTRODUCTION

This is a Request for Information (RFI) issued by the Indiana Department of Administration (IDOA) in conjunction with the Indiana Family and Social Services Administration (FSSA) and the Indiana Cord Blood Bank (ICBB). This RFI requests responses from potential contractors to operate a public cord blood banking facility (the “Bank”). It is the intent of IDOA to solicit responses to this Request for Information (RFI) in accordance with the statement of work and specifications contained in this document. Neither this RFI nor any response (proposal) submitted hereto are to be construed as a legal offer.

BACKGROUND

House Enrolled Act 1172 and IC 12-31 call for the Indiana Family and Social Services Administration (FSSA) to create a non-profit corporation that will form and operate the Bank. Accordingly, FSSA has created the ICBB, which is offering this RFI. Operation of the Bank will facilitate life-saving transplants and enhance research opportunities in Indiana, thereby bringing the State to the forefront of life sciences research, promoting economic development, and enhancing the public health and treatment of critically ill citizens.

The Bank will accept donated umbilical cord blood, placenta, and other postnatal tissue. These donations will be collected, processed, stored, and maintained at no cost to the donors. Donations that are of transplantable quality will be entered on the National Marrow Donor Program (NMDP) Registry and made available for transplant to patients with conditions such as leukemia, lymphoma, and other life-threatening diseases. All rights in the donations shall transfer to ICBB upon donation; donations that are ineligible for transplant may be made available to third parties for research purposes.

OBJECTIVE

This RFI will select a contractor or contractors to operate the Bank on the ICBB’s behalf. ICBB intends to sign a contract with one or more Respondent(s) to fulfill the requirements in this RFI.

The term of the contract shall be for a period of two (2) years from the date of contract execution. There may be multiple one (1) year renewals, at ICBB’s option, in accordance with Attachment A.

The scope of work is divided into four primary activities. Respondents may propose to perform all functions listed below, or only one, two, or three of the four. However, the ICBB encourages Respondents who cannot perform all responsibilities themselves to subcontract as needed to propose a complete solution. Responsibilities are:

1. Collect donations. Develop a network of participating Indiana physicians, hospitals, and clinics at which pregnant women may donate postnatal tissue; obtain patients' informed consent; collect donations of postnatal tissue; transfer the tissue to the storage contractor
2. Process samples. Test donations to determine whether they meet the NMDP's standards for transplantable tissue; perform tissue typing and enter samples into the NMDP's donor registry
3. Store samples. Store the postnatal samples collected above; operate a facility meeting the NMDP's stringent requirements for cord blood banks; maintain the samples until such time as they are used for transplant or research; transfer samples to and receive samples from the processing contractor; fill orders from transplant centers and researchers
4. Outreach and Development. Comply with the NMDP's requirements for a Recruitment Group; publicize the ICBB among the medical community, expectant mothers, and life sciences researchers; explain the benefits and limits of public cord blood banking to potential donors; and ensure patients have the information they need to make informed decisions

More detail about each of these responsibilities can be found below.

SPECIFIC NEEDS

Using Attachment D, the Technical Response Form, will help Respondents ensure that they address every point below

RFI language should not be repeated within the response. Where appropriate, supporting documentation may be referenced by a page and paragraph number. However, when this is done, the body of the technical proposal must contain a meaningful summary of the referenced material. The referenced document must be included as an appendix to the technical proposal with referenced sections clearly marked. If there are multiple references or multiple documents, these must be listed and organized for ease of use by the State.

1. All Sections. All Respondents must address the following requirements:
 - 1.1 Indicate if the Respondent is proposing a complete set of cord blood banking services or if it is submitting a partial proposal. Indicate which portions of this scope of work the Respondent is proposing to fulfill, which portions it proposes to subcontract, and which it is not proposing to serve.

Complete the following table; each row should be completely filled out.

Scope of Services	Respondent Will Perform (Yes/No)	Respondent Will Subcontract (Yes/No; if yes, give subcontractor's name)	Not Offered (Check if not offered under this RFI)
<i>Example: 2. Collect Donations</i>	No	Yes, to ABC Corp.	--
<i>Example: 3. Store Donations</i>	Yes	No	--
<i>Example: 4. Process Donations</i>	Yes	No	--
<i>Example: 5. Outreach/Development</i>	No	No	✓
2. Collect Donations			
3. Process Donations			
4. Store Donations			
5. Outreach/Development			

1.2 Comply with IC 12-31-1 and 12-31-2.

Confirm that the Respondent will comply with IC 12-31-1 and IC 12-31-2 in their entirety.

Confirm that the Respondent is a nonprofit corporation and meets all requirements and responsibilities set forth in IC 23-17.

1.3 Support the ICBB's preparation of the reports required by IC 12-31-1-9 by reporting quarterly to ICBB at least the number of postnatal donations collected, the number used for transplant, and the number used for research.

Confirm that the Respondent will provide quarterly reports to the ICBB covering topics and in a format to be mutually agreed upon between the parties. Submit sample reports similar to those the Respondent proposes to offer the ICBB. Anonymized reports from current clients or reports containing fabricated data that demonstrate the proposed structure are acceptable.

1.4 Maintain strict separation between public and private cord blood banking facilities and operations.

Describe Respondent's private cord blood banking operations, if any. Explain the Respondent's plan to avoid any potential conflict of interest from operating a private bank (or banks) as well as the ICBB Bank.

As applicable, describe the Respondent's plan to recruit donors only for inclusion in the NMDP registry, and not Respondent's private bank(s). Describe how the Respondent's private cord blood samples, if any, would be kept separate from the Bank's public samples, and what facilities (if any) would be shared. Describe the duties of the Respondent's staff, and whether

proposed staff would be fully dedicated to the Bank or shared with the Respondent's private bank(s).

2. Collect Donations. Respondents proposing to collect donations of postnatal fluid and tissue, or use subcontractors for this function, must address the following requirements:

- 2.1 Build a network consisting of participating physicians, hospitals, ambulatory surgical centers, health clinics, maternity homes, and nurse midwives. Pregnant women will need to give birth with one of the participating providers in order to be able to make a donation of postnatal tissue.

Will the Respondent's network of participating providers initially be limited to certain geographic communities within Indiana? Would it be statewide? To provide the greatest public benefit, would it focus on providers serving diverse populations that are under-represented on the NMDP registry?

Understanding the ICBB's goal of providing a statewide public bank, how quickly will the Respondent "scale up" to a complete network of all interested hospitals and providers statewide?

Will the Respondent's network include any providers located outside of Indiana?

- 2.2 Collect postnatal tissue donations from willing patients, in compliance with NMDP and FDA standards, and transfer the samples to the storage and/or processing contractors if applicable.

Describe the Respondent's capabilities and experience collecting postnatal fluid and tissue donations from newborn deliveries.

Will the Respondent's personnel collect donations, or will it rely on providers to collect donations? What safeguards will be in place to ensure patient confidentiality and donation quality?

Describe the Respondent's plan to transfer donations to the processing and/or storage contractor(s).

- 2.3 Donations must be collected at no cost to the donor.

Confirm that donations will be collected at no cost to the donor.

- 2.4 Comply with the applicable NMDP Cord Blood Bank Participation Criteria, as updated from time to time, including all applicable standards, policies,

procedures, participation agreements, and riders. The current requirements are attached as Attachment E, but may be updated by the NMDP.

Describe the Respondent's ability to comply with the applicable criteria, including at least the following:

Indicate whether the Respondent is already certified as an NMDP Cord Blood Bank or whether the Respondent has applied for certification. When does the Respondent expect its NMDP certification to be complete? If certified, how long has the Respondent been participating in the NMDP?

Provide the resume and a summary of qualifications for the Respondent's proposed Medical Director, as well as staff who would oversee collection of donated samples.

Briefly summarize the Respondent's experience serving the three (3) clients it selected for references above.

- 2.5 Work with the ICBB to develop transition plans for the eventual end of the contract awarded as a result of this RFI.

Indicate the Respondent's willingness to develop a mutually agreeable transition plan, as required by the contract in Attachment A. The transition plan will cover such topics as continued prompt delivery of donations to the storage and/or processing contractor(s) at and near the end of the contract. Describe the Respondent's experience with end-of-contract transitions.

3. Process samples. This includes testing donated samples to determine if they are of transplantable quality or suitable for research and entering samples into the NMDP registry. Respondents proposing to process donations of postnatal tissue, or use subcontractors for this function, must address the following requirements:

- 3.1 Obtain donated samples from the storage and/or collection contractor(s).

Describe the Respondent's plan to coordinate with the storage and/or collection contractor(s) to ensure that donations are processed quickly, accurately, and returned to storage in the same condition at which they were processed.

- 3.2 Test donations to determine if they meet the standards for transplantable units.

Describe the Respondent's process for determining whether a given sample meets the standards for potential transplant. Indicate the Respondent's

willingness to perform all necessary tests, including those that may be added to the NMDP's list from time to time, at no cost to the donor.

- 3.3 Test and tissue type all donations, whether they are to be used for research or transplant.

Indicate what tests the Respondent will perform on all donations. If a sample is known not to be of transplantable quality, what tests will Respondent perform, and in what order? Will it perform any that are not specifically required by the NMDP? What test results can researchers use to screen donated samples for potential research purposes?

- 3.4 Maintain strict patient confidentiality. Anonymize donations as appropriate.

Describe the Respondent's secure environment for confidential record storage and its plan to maintain donor confidentiality.

- 3.5 Test and process donations at no cost to the donor.

Confirm that donations will be tested, processed, and entered into the NMDP Registry at no cost to the donor.

- 3.6 Comply with the NMDP Cord Blood Bank Participation Criteria, as updated from time to time, including all applicable standards, policies, procedures, participation agreements, and riders. The current requirements are attached as Attachment E, but may be updated by the NMDP.

Describe the Respondent's ability to comply with the applicable criteria, including at least the following:

Indicate whether the Respondent is already certified as an NMDP Cord Blood Bank or whether the Respondent has applied for certification. When does the Respondent expect its NMDP certification to be complete? If certified, how long has the Respondent been participating in the NMDP?

Provide the resume and a summary of qualifications for the Respondent's proposed Medical Director, as well as staff who would oversee processing of donated samples.

Briefly summarize the Respondent's experience serving the three (3) clients it selected for references above.

- 3.7 Work with the ICBB to develop transition plans for the eventual end of the contract awarded as a result of this RFI.

Indicate the Respondent's willingness to develop a mutually agreeable transition plan, as required by the contract in Attachment A. The transition plan will cover such topics as the maintenance of confidential records, continued storage and access to donations at and near the end of the contract, transferring responsibilities to future contractor(s), and similar topics. Describe the Respondent's experience with end-of-contract transitions.

4. Store Donations. Respondents proposing to store postnatal donations and fulfill orders for transplant and/or research purposes, or use subcontractors for this function, must address the following requirements:

- 4.1 Accept donations from the collection contractor, in accordance with industry best practices.

Describe Respondent's plan to coordinate with the collection contractor, if necessary, to ensure donated samples are of high quality at the time the Respondent begins storing them in its facility.

Describe the location and capacity of the Respondent's storage facility. Will the Respondent guarantee a certain capacity to the ICBB? How will the Respondent build up its capacity to store additional samples as the Bank develops over time?

- 4.2 Store donations at no cost to the donor.

Confirm that donations will be stored for the length of the contract, including any renewals, at no cost to the donor.

- 4.3 Fulfill orders from transplant centers for donated tissue to be used in transplants.

Describe Respondent's ability to promptly fill orders from transplant centers and to ensure tissue selected for transplant arrives on time, in sufficient quantity, and meeting the same stringent quality requirements that designated it as transplantable when it was originally processed.

- 4.4 Fulfill orders from research centers and other entities approved by the ICBB that will use the postnatal donation to promote medical advances, life science research, or biotechnology research.

Describe Respondent's ability to promptly fill orders from researchers and to ensure tissue arrives on time, in sufficient quantity, and meeting the same stringent quality requirements that designated it as suitable for research when it was originally processed.

- 4.5 Comply with the NMDP Cord Blood Bank Participation Criteria, as updated from time to time, including all applicable standards, policies, procedures, participation agreements, and riders. The current requirements are attached as Attachment E, but may be updated by the NMDP.

Describe the Respondent's ability to comply with the applicable criteria, including at least the following:

Indicate whether the Respondent is already certified as an NMDP Cord Blood Bank or whether the Respondent has applied for certification. When does the Respondent expect its NMDP certification to be complete? If certified, how long has the Respondent been participating in the NMDP?

Provide the resume and a summary of qualifications for the Respondent's proposed Medical Director, as well as staff who would oversee storage of donated samples.

Briefly summarize the Respondent's experience serving the three (3) clients it selected for references above.

- 4.6 Work with the ICBB to develop transition plans for the eventual end of the contract awarded as a result of this RFI.

Indicate the Respondent's willingness to develop a mutually agreeable transition plan, as required by the contract in Attachment A. The transition plan will cover such topics as the continued storage of donations at and near the end of the contract, transferring stored donations to future contractor(s), and similar topics. Describe the Respondent's experience with end-of-contract transitions.

5. Outreach and Development. Respondents proposing to publicize the Bank, or use subcontractors for this function, must address the following requirements:

- 5.1 Promote public awareness concerning the following:

- (1) A pregnant woman's option to make a postnatal donation upon the birth of a newborn infant.
- (2) The medical benefits of postnatal tissue and postnatal fluids.
- (3) The importance of donating umbilical cord blood to the public umbilical cord blood bank.

Explain the Respondent's plan to publicize the Bank. Describe experience publicizing similar initiatives or entities in the past.

Confirm the Respondent's ability to host a website dedicated to the Bank, add/remove content as directed by the ICBB, and maintain the website for the duration of the contract term. Include a mockup or sample website with the proposal. (Note that FSSA already has several domain names reserved; Respondents will use their own servers but will not need to secure a URL).

5.2 Pursuant to IC 12-31-2-4, develop, update, and disseminate written material that includes the following:

(1) Information concerning the option that is available to pregnant women to make a postnatal donation upon the birth of a newborn infant.

(2) An explanation of the benefits of public umbilical cord blood banking.

(3) The benefits of umbilical cord blood in accordance with the National Marrow Donor Program or another federal Food and Drug Administration approved protocol and the use of umbilical cord blood for medical treatment, including the following:

(A) A list of the diseases or conditions that have been treated through the use of umbilical cord blood.

(B) A list of the diseases or conditions for which scientific research indicates that treatment through the use of umbilical cord blood is promising.

(4) Information on the public umbilical cord blood bank.

(5) Information concerning the process by which postnatal tissue and postnatal fluid are collected and the steps that a pregnant woman must take before her child is born to arrange to have the postnatal tissue and postnatal fluid collected and donated.

Describe the Respondent's ability to meet the requirements above. Include sample written material that the Respondent proposes to disseminate to publicize the Bank.

Confirm that the Respondent will modify or update its written material as directed by the ICBB.

Describe the Respondent's plan to update its written material. How often will material be updated? What procedures will the Respondent use to obtain ICBB approval before disseminating updated information?

5.3 Distribute the material to the following persons that treat pregnant women:

(A) Physicians licensed under IC 25-22.5.

(B) Participating hospitals.

(C) Ambulatory surgical centers.

(D) Health clinics.

(E) Maternity homes registered under IC 16-26-1.

(F) Nurse midwives licensed under IC 25-23-1-13.1

Describe the Respondent's plan to distribute material to the persons named above. How does the Respondent propose to become aware of changes to the collection contractor's network of participating providers?

5.4 Maintain strict separation between any public and private cord blood banking operations. This is especially crucial in the outreach and development area.

Describe the Respondent's private cord blood banking operations, if any. Describe the Respondent's plan to ensure that donors are recruited solely for participation in the NMDP registry, and not any private bank operated by the Respondent.

5.5 Comply with the NMDP Recruitment Group Participation Criteria, as updated from time to time, including all applicable standards, policies, procedures, participation agreements, and riders. The current requirements are attached as Attachment F, but may be updated by the NMDP.

Describe the Respondent's ability to comply with the applicable criteria, including at least the following:

Indicate whether the Respondent is already certified as an NMDP Recruitment Group or whether the Respondent has applied for certification. When does the Respondent expect its NMDP certification to be complete?

Describe the Respondent's access to a NMDP donor center's medical director for assistance with donor suitability and eligibility issues. Provide the resume and a summary of qualifications for the Respondent's proposed staff who would publicize the Bank.

Briefly summarize the Respondent's experience serving the three (3) clients it selected for references above.

5.6 Work with the ICBB to develop transition plans for the eventual end of the contract awarded as a result of this RFI.

Indicate the Respondent's willingness to develop a mutually agreeable transition plan, as required by the contract in Attachment A. The transition plan will cover such topics as publicizing the Bank's continued operation during contract transition(s), explaining transition procedures to potential donors, and similar topics. Describe the Respondent's experience with end-of-contract transitions.

Additional Considerations:

- Respondent's qualifications and related experience necessary to operate the Bank
- Agreement to meet the contractual requirements of Attachment A
- Ability to operate the Bank in a cost-effective manner; see Attachment B
- Demonstration of financial stability and industry presence; see Attachment C
- Comparable project references of similar scope and size

ATTACHMENTS

Respondents should submit responses to the RFI using Attachment B (the Cost Proposal), Attachment C (the Business Proposal), and Attachment D (the Technical Proposal). Other attachments noted below are for information only.

Attachment	Description
Attachment A	Sample Contract
Attachment B	Cost Proposal Response Form (RESPONSE REQUIRED)
Attachment C	Business Proposal Response Form (RESPONSE REQUIRED)
Attachment D	Technical Proposal Response Form (RESPONSE REQUIRED)
Attachment E	National Marrow Donor Program® Cord Blood Bank Participation Criteria
Attachment F	National Marrow Donor Program® Recruitment Group Participation Criteria

RESPONSES

Firms interested in providing information to IDOA and FSSA should submit **an original hard-copy, an original CD-ROM (marked “Original”) and twelve (12) complete copies of the response on CD-ROM**. Unnecessarily elaborate brochures or other presentations, beyond those necessary to present a complete and effective response, are not desired. All proposals must be addressed to:

Stephanie Taylor
Indiana Department of Administration
Procurement Division
402 West Washington Street, Room W478
Indianapolis, IN 46204

All responses must be received no later than **3:00 p.m. Eastern Time on July 23, 2010**. The outside of the package (envelope or box) should be clearly marked:

“RESPONSE TO REQUEST FOR INFORMATION 11-2”

Any information received after the due date and time will not be considered. Any late submissions will be returned, unopened, to the Respondent upon request. All rejected submissions not claimed within 30 days of the proposal due date will be destroyed.

Responses will be considered public information once a contract(s) is awarded. If a

contract is not awarded, the responses are considered public once the decision is made.

No more than one proposal per Respondent may be submitted.

The State and ICBB accept no obligations for costs incurred by Respondents in anticipation of being awarded a contract.

If you hand-deliver solicitation responses:

To facilitate weapons restrictions at Indiana Government Center North and Indiana Government Center South, the public must enter IGC buildings through a designated public entrance. The public entrance to Indiana Government Center South is located at 302 W. Washington St. (the eastern-most Washington St. entrance). This entrance is equipped with metal detectors and screening devices monitored by Indiana State Police Capitol Police.

Passing through the public entrance may take some time. Please be sure to take this information into consideration if your company plans to submit a solicitation response in person.

If you ship or mail solicitation responses: United States Postal Express and Certified Mail are both delivered to the Government Center Central Mailroom, and not directly to the Procurement Division. It is the responsibility of the Respondent to make sure that solicitation responses are received by the Procurement Division at the Department of Administration's reception desk on or before the designated time and date. Late submissions will not be accepted. The Department of Administration, Procurement Division clock is the official time for all solicitation submissions.

Question/Inquiry Process. All questions/inquiries regarding this RFI must be submitted in writing by the deadline of **3:00 p.m. Eastern Time on July 12, 2010.**

Questions/Inquiries may be submitted via email to RFP@idoa.IN.gov and must be received by Procurement Division by the time and date indicated above.

Following the question/inquiry due date, Procurement Division personnel will compile a list of the questions/inquiries submitted by all Respondents. The responses will be posted to the IDOA website. The question/inquiry and answer link will become active after responses to all questions have been compiled. Only answers posted on the IDOA website will be considered official and valid by the State. No Respondent shall rely upon, take any action, or make any decision based upon any verbal communication with any State employees or ICBB representatives.

Inquiries are not to be directed to any staff member of FSSA or representatives of the ICBB. Such action may disqualify Respondent from further consideration for a contract resulting from this RFI.

Please note that Stephanie Taylor is the State's single point of contact for this RFI.

If it becomes necessary to revise any part of this RFI, or if additional information is necessary for a clearer interpretation of provisions of this RFI prior to the due date for

submissions, an addendum will be posted on the IDOA website. If such addenda issuance is necessary, the Procurement Division may extend the due date and time to accommodate such additional information requirements, if required.

Pricing. Pricing on this RFI must be firm and remain open for a period of not less than 180 days from the submission due date.

Please provide your pricing proposal by populating the Cost Proposal (Attachment B). Submit Attachment B in Microsoft Excel format. The form has several tabs; be sure to complete all applicable worksheets.

Clarifications and Discussions. The State and ICBB reserve the right to request clarifications on information submitted to the State. The State and ICBB also reserve the right to conduct discussions, either oral or written, with Respondents. These discussions could include requests for additional information, requests for cost or technical proposal revision, etc. Additionally, in conducting discussions, the State and ICBB may use information derived from proposals submitted by competing respondents only if the identity of the respondent providing the information is not disclosed to others. The State will provide equivalent information to all Respondents which have been chosen for discussions. Discussions, along with negotiations with responsible Respondents may be conducted for any appropriate purpose.

The Procurement Division will schedule all discussions. Any information gathered through oral discussions must be confirmed in writing.

A sample contract is provided in Attachment A. Any requested changes to the sample contract must be submitted with your response. The State and ICBB reserve the right to reject any of these requested changes. The State and ICBB expect that any material elements of the contract will be substantially finalized prior to contract award.

The State and ICBB may request best and final offers from those Respondents determined by the State to be reasonably viable for contract award. However, the State and ICBB reserve the right to award a contract on the basis of initial proposals received. Therefore, each proposal should contain the Respondent's best terms from a price and technical standpoint.

Following evaluation of the best and final offers, the State and ICBB may select for final contract negotiations/execution the offers that are most advantageous, considering cost and the evaluation criteria in this RFI.

The State may request a site visit to a Respondent's working support center to aid in the evaluation of the Respondent's proposal.

Key Dates. The following timeline is only an illustration of this RFI process. The dates associated with each step are not to be considered binding. These dates are commonly subject to change.

Anticipated RFI Dates:

Activity	Date
Issue of RFI	July 2, 2010
Deadline to Submit Written Questions	July 12, 2010
Response to Written Questions/RFI Amendments	July 16, 2010
Due Date for Submissions	July 23, 2010
<i>The dates for the following activities are target dates only. These activities may be completed earlier or later than the date shown.</i>	
Response Evaluation	August 13, 2010
Discussions/Clarifications (if necessary)	August 13 to August 20, 2010
Oral Presentations (if necessary)	August 27, 2010
Best and Final Offers (if necessary)	August 27, 2010
Contract Award	September 3, 2010

The Secretary of FSSA or her designee will, in the exercise of her sole discretion, determine which RFI submission(s) offer the best means of servicing the interests of the State. The exercise of this discretion will be final.